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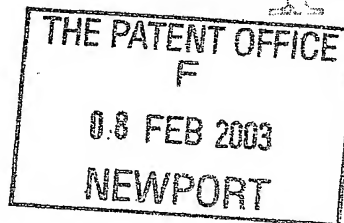
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1. Your reference SJB/P11650

2. Patent application number 0302944.4  
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3. Full name, address and postcode of the or of each applicant (underline all surnames)  
DePuy International Limited  
St Anthony's Road  
Beeston  
Leeds  
LS11 8DT

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation England 06604733004

4. Title of the invention A KNEE JOINT PROSTHESIS

5. Name of your agent (if you have one)

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)  
Urquhart-Dykes & Lord  
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LEEDS  
LS2 8PA

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8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:  
a) any applicant named in part 3 is not an inventor, or  
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# Patents Form 1/77

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Continuation sheets of this form

Description

10

Claim(s)

2

Abstract

Drawing(s)

6 + 6 SW

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Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

1

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

*S J Belcher*

Date

*Feb 07*

12. Name and daytime telephone number of person to contact in the United Kingdom

S J BELCHER - 0113 245 2388

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DUPLICATE

-1-

## A KNEE JOINT PROSTHESIS

This invention relates to a knee joint prosthesis which comprises a tibial component and a femoral component.

Flexing of a knee joint involves a combination of rotation and translation of the femoral component relative to the tibial component. The femoral component of a whole knee joint prosthesis has a bearing surface provided by medial and lateral condyles. The surfaces of the condyles are convex. The condyles bearing surfaces act against the tibial component, directly or indirectly through a meniscal component. It is common for a knee joint prosthesis to include a meniscal component. This is frequently made from a material which permits low friction movement between the tibial and femoral components. For example, when the femoral component is formed from a metal such as a cobalt chromium based alloy, the bearing component can be formed from a polymer such as ultrahigh molecular weight polyethylene. The face of the meniscal component which faces towards the femoral component will generally have a pair of recesses in which the convex bearing surfaces of the condyles can articulate as the joint is flexed. In some knee joint prostheses, the tibial component will often have a planar bearing surface which faces towards the femur. A meniscal component will then have a planar lower surface which is also planar so that the meniscal component can slide relative to the tibial component as the joint is flexed. In other knee joint prostheses, the meniscal component can be allowed to rotate about the tibial axis but be fixed against translation. In yet other knee joint prostheses, the meniscal component can be fixed relative to the tibial component.

The stability of the joint through moderate flex angles is provided by the surface to surface contact between the curved surfaces of the condyles and the recesses in the meniscal component. Ligaments extending between the tibia and femur can control relative rotational and translational movement between the two bones. However, especially when it is anticipated that the joint will experience large flex angles, additional stability can be provided by a post which extends from the tibial component in a direction away from the tibia, and a cam on the femoral component which extends between the condyles at or towards their posterior ends. The cam can contact the post, at least at moderate to high flex

angles, and thereby restrict translation of the femoral component relative to the tibial component. The post can be provided on a bearing component of the knee. The material of the bearing component is often selected for its low coefficient of friction when in contact with the metallic bearing surface of the femoral or tibial component. The properties of the selected material might not always be optimised for bearing the load which is applied by the cam at high flex angles.

While contact between a post on the tibial component and a cam on a femoral component is intended to restrict translation of the femoral component relative to the tibial component, it will generally be desired that it should not restrict relative rotation between the femoral and tibial components. Accordingly, the area of contact between the cam and the post will be kept to a minimum, especially as close as possible to point contact. This can be achieved by arranging both the post and the cam to have rod or bar-like shapes, which are convex at the points where they are in contact when viewed along their lengths, and for them to intersect roughly perpendicular to one another.

The present invention provides a knee joint prosthesis in which the femoral bearing surface is provided in part by a cam which extends between the condyles, which is concave where it contacts a post on the tibial component at high flex angles.

Accordingly, in one aspect, the invention provides a knee joint prosthesis which comprises:

- a. a tibial component which has a bone contact surface for contacting a patient's resected tibia, and an opposite bearing surface, and a post extending from the bearing surface in a direction generally away from the bone contact surface, and
- b. a femoral component which has a bearing surface provided by medial and lateral condyles, and by a cam which is located between the condyles at or towards their posterior ends,

in which the condyles of the femoral bearing surface act against the bearing surface of the tibial component, directly or indirectly, during flexing of the knee and the cam on the

femoral component acts against the post on the tibial component at high flex angles, the surface of the post which is contacted by the cam at high flex angles being convex when the post viewed generally perpendicular to the tibial bone contact and bearing surfaces, and the femoral bearing surface which is provided by the cam being concave where it contacts the convex surface of the post at high flex angles.

The knee joint prosthesis of the present invention has been found to give rise to the advantage that the ability of the post to bear the loads imposed on it by the cam at high flex angles is enhanced. This has been found to arise from the larger area of contact between the cam and the post at high flex angles than is available with prostheses in which the surface of the cam is not concave where it contacts the post.

Furthermore, the increased area of contact between the cam and the post can mean that the joint is more stable, and less prone to dislocation, than is the case in which the contact between a cam and post is restricted to point contact.

The cam can be generally bar-like having a generally rounded cross-section when viewed along its length, at least around those parts of its periphery at which it contacts the post on the tibial component. The cam can be connected to the condyles at its opposite ends. It can also be connected to other parts of the femoral component at other points along its length, and possibly along its entire length.

The cam will appear to be concave when viewed sagittal (from one side) and transversely (along the femoral axis) in the region in which it is intended to contact the post at high flex angles, and convex around the other parts of the periphery at which it contacts the post at other flex angles. Preferably, the radius of curvature of the cam in the centre of the concave region, when viewed from one side, is at least about 25 mm, more preferably at least about 30 mm, especially at least about 37 mm. Preferably, the said radius of curvature is not more than about 60 mm, more preferably not more than about 50 mm, especially not more than about 43 mm. In a preferred embodiment, the radius of curvature of the cam in the centre of the concave region, when viewed from one side, is about 40 mm.

Preferably, the depth of the concave portion of the cam, measured relative to the surface of the cam at each side of the concave portion, is at least about 0.5 mm. Preferably, the said depth is not more than 1.2 mm, more preferably not more than about 1.0 mm.

The transition between the convex surface of the cam and the concave surface in the region in which it will contact the post at high flex angles should be carefully shaped so that the area of contact between the cam and the post does not decrease significantly as the angle of flex increases to bring the concave region of the cam into contact with the post. This can be achieved by making the edge of the concave region rounded. The radius of curvature of the concave region rounded edge can vary around the concave region. The radius of curvature can be greatest at the posterior edge. For example, the radius of curvature at the anterior edge of the concave region is preferably at least about 1.0 mm, more preferably at least about 1.5 mm, especially at least about 1.75 mm, for example about 2.0 mm. The radius of curvature at the anterior edge is preferably not more than about 3.0 mm, more preferably not more than about 2.5 mm. The radius of curvature at the posterior edge of the concave region is preferably not more than about 6.0 mm, more preferably not more than about 5.0 mm, for example not more than about 4.75 mm. The radius of curvature at the posterior edge is preferably at least about 3.0 mm, more preferably at least about 4.0 mm.

Preferably, the bearing surface on the cam is configured so that the surface is concave where it contacts the post when the flex angle between the femur and the tibia is at least about  $130^{\circ}$ , more preferably at least about  $120^{\circ}$ . The bearing surface on the cam will preferably then be concave where it contacts the post at all flex angles greater than about  $120^{\circ}$ , preferably at all angles greater than about  $130^{\circ}$ , for example at all angles up to about  $150^{\circ}$ , preferably at all angles up to about  $155^{\circ}$ . Preferably, the area of contact between the bearing surfaces of the cam and the post increases as the flex angle increases from an angle of not less than about  $115^{\circ}$ , preferably not less than about  $120^{\circ}$ , so that the area of contact reaches a maximum when the flex angle is not less than about  $145^{\circ}$ , preferably not less than about  $150^{\circ}$ . The area of contact will increase from a shape which approximates to a point, to a shape which is generally rounded, especially oval. As the area of contact increases through the increasing flex angle, the size of the oval area of contact increases.

The flex angle at which the concave portion of the cam bearing surface engages the post is determined by the orientation angle of the cam. The orientation angle is the angle between the sagittal plane and a line extending normally through the centre of the concave portion. Preferably, the orientation angle is at least about  $15^{\circ}$ , more preferably at least about  $20^{\circ}$ . Preferably, the orientation angle is not more than about  $30^{\circ}$ , more preferably not more than about  $25^{\circ}$ . Preferably, the orientation angle is about  $22^{\circ}$ . When the flex angle is about  $22^{\circ}$ , contact between the post concave portion of the cam can occur at flex angles greater than about  $120^{\circ}$ , with contact area at a flex angle of about  $155^{\circ}$ .

When the cam is bar-like and extends between the condyles, it can be preferred for the area of the cam at which it engages the post to increase so that, when the area is at its maximum, it extends to a point which is not more than 1.5 mm from the ends of the bar where it joins the condyles, preferably not more than 1.0 mm.

The tibial component can comprise an implant part and a bearing part. The implant part and the bearing part can be made from different materials. For example, the implant part can be made from a metal such as a cobalt chromium alloy or a titanium based alloy. The bearing part can be made from a polymer such as an ultrahigh molecular weight polyethylene (UHMWPE). The bearing part will often be fixed to the implant part so that it does not move relative to it during articulation of the knee. For example, the bearing part can fit into a recess which is defined by an upstanding wall, extending around at least part of the periphery of the tibial part. Alternatively (or in addition), the implant part and the bearing part can fit together by an arrangement which comprises at least one interdicting boss and recess. It will generally be preferred that the bearing part is fixed against translation relative to the implant part, but can rotate relative to it. This can be achieved by means of a peg on the bearing part which is received in an axially extending bore in the implant part. For example, the implant part can include a hollow peg which can be received in an appropriately shaped cavity in the resected tibia. The space within the peg on the implant part can receive a peg on the bearing part. Preferably the pegs on the two parts, and the recess within the peg on the implant part, are conical with a circular cross-section.

A knee joint prosthesis in which the tibial component comprises implant and bearing parts, in which the bearing part is fixed against translation relative to the implant part, is sold under the trade mark SIGMA by DePuy Orthopaedics Inc of Warsaw, Indiana, USA.

The post can be provided on the bearing part of an tibial component which comprises separate implant and bearing parts. A bearing part which includes a post will generally be formed as a single piece which consists of the same material throughout (for example a polymeric material such as UHMWPE).

The height of the post will be selected to ensure that the cam will not ride over the top of the post at high flex angles. The width and depth of the post (measured parallel to the sagittal plane) should be sufficient to ensure that the post can withstand loads imposed on it by the cam when the knee joint is flexed. The appropriate selection of these design features is known, for example as in the knee joint prostheses sold by Orthomet Inc under the trade mark AXIOM, and by Smith & Nephew Richards under the trade mark GENESIS (Posterior Stabilised).

Preferably, the surface of the post which is contacted by the cam at high flex angles is convex when viewed from above (viewed generally along the tibial axis). Preferably, the surface of the post which is contacted by the cam is flat, or possibly concave, when viewed sagittally (from one side).

It has been found that, by appropriate shaping of the cam and the post, the area of contact between the two can be at least about  $50 \text{ mm}^2$ , preferably at least about  $75 \text{ mm}^2$ , for example from  $80 \text{ mm}^2$  and up to  $120 \text{ mm}^2$  or more, at maximum flex angles. This is very much greater than can be achieved with knee prosthesis designs in which the surface of the cam is convex. As a result, the post is better able to bear the loads imposed on it by the cam at high flex angles. Furthermore, the increased area of contact between the cam and the post can mean that the joint is more stable, and less prone to dislocation, than is the case in which the contact between a cam and post is restricted to point contact.

Embodiments of the invention will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 is an exploded view of a knee prosthesis according to the present invention.

Figure 2 is a sectional elevation through the femoral component shown in Figure 1, on the line II-II.

Figure 3 is an enlarged view showing the portion of the cam on the femoral component in which the bearing surface is concave along the direction marked by the arrow IV

Figure 4 is a partial cross-section through the cam on the femoral component on the line IV-IV.

Figures 5a and 5b are isometric and side elevation views of the bearing component shown in Figure 1.

Figures 6a to 6e are views from one side showing how the femoral component of a knee joint prosthesis of the kind shown in Figure 1 articulates against the tibial component.

Figure 7 is a graph which depicts the variation in contact area between the femoral and tibial components of a knee joint prosthesis with changes in the angle of articulation of the joint.

Referring to the drawings, Figure 1 shows a knee joint prosthesis which comprises a femoral component 2 and a tibial component. The tibial component comprises an implant part 4 and a bearing part 6. The femoral component and the implant part of the tibial component are formed from a cobalt chromium based alloy. The implant part of the tibial component has a downwardly extending peg 8 which can be received in an appropriately shaped cavity in the resected tibia. The upward surface 10 is generally planar. It has a central opening 12 which communicates with a conical bore within the downwardly extending peg 8. A notch 9 is formed in the implant part of the tibial component to accommodate ligament tissue.

The femoral component has medial and lateral condyles 14, 16, each of which has a bearing surface with appropriately smooth finish. There is a recess 18 between the condyles.

The recess is defined posteriorly by a bar 20 which extends between the condyles. The bar is generally rounded in cross-section when viewed from one side along the medial-lateral axis. It has a finished bearing surface around at least part of its curved surface, at least in a central region which provides a cam.

The bearing part 6 of the tibial component is made from a polymeric material such as ultra-high molecular weight polyethylene. Its lower surface is planar and has a conical peg depending from it. The peg is sized so that it fit snugly within the conical bore 12 in the implant part of the tibial component. The peg and the bore have a circular cross-section so that the bearing part can rotate relative to the implant part.

The upper surface of the bearing part has two concave recesses 22, 24 formed in it in which the condyles 14, 16 can be received, and can slide during articulation of the joint. A post 26 extends upwardly from the bearing part. The post has a bearing surface 28 on its posteriorly facing edge. When viewed from above along the tibial axis, the posteriorly facing surface of the post is convex. When viewed from the side, the posteriorly facing surface of the post is straight, or slightly concave.

One of the condyles 14 of the femoral component 2 is visible in Figure 2. Also visible is the bar 20. The bar can be seen to have a generally rounded shape when viewed from the side. The bar is formed integrally with a web 19 which extends between the condyles, defining a recess between the condyles into which the post extends during flexing of the joint.

The concave portion 32 of the bar is shown in more detail in Figures 3 and 4. As shown in Figure 3, the concave portion 32 has rounded transitions at its edge. The radius of curvature at the rounded transition at the posterior edge is greater than at the other edges. The radius at the posterior edge 34 is about 4.6 mm, and the radii at the anterior, medial and lateral edges is about 2.0 mm. The concave portion extends to within about 1.5 mm of the condyles at each end of the bar 20.

As shown in Figure 4, the concave portion of the bar is rounded when it is viewed in a direction which is parallel to the bearing surface of the post (when the concave portion and the post are aligned in contact with one another at maximum flexing of the joint). The radius of curvature is about 40 mm. This is little more than the radius of curvature of the post (when viewed from above along the tibial axis) with which it is in contact at high flex angles. When the concave portion of the bar is viewed from one side (as in Figure 2), it is approximately straight.

The bar is polished on that part of its surface which is intended to contact the post during articulation of the knee. There is a concave portion 32 in that part of the bar which contacts the post at high flex angles.

Figures 5a and 5b show the bearing part 6 of the tibial component. The bearing surface 28 of the post 26 is essentially planar towards its upper end (as shown in Figure 5b). The bearing surface is also essentially planar along the medial-lateral axis, that is when viewed from above (along the line defined by the arrow "A").

As shown in Figure 6a, at moderate flex angles (up to about  $90^\circ$ ), contact between the femoral and tibial components is restricted to contact between the condylar bearing surfaces 14, 16 of the femoral component which engage the recesses 22, 24 in the bearing part of the tibial component. During flexing of the joint through moderate flex angles, the femoral component can rotate and translate relative to the tibial component. At a flex angle of about  $90^\circ$ , the cam provided by the bar 20 engages the post 26 on the bearing component. The action of the post against the cam can control further translational movement of the femoral component relative to the tibial component, in the plane thereof, so that continued flexing of the knee is restricted largely to a pivoting motion, as shown in sequence in Figures 6b to 6d.

As shown in Figure 6b, at a flex angle of about  $90^\circ$ , the curved bearing surface on the bar 20 engages the bearing surface on the post 26, the point marked "C". At moderate flex angles (up to  $115^\circ$  or  $125^\circ$ ), the bearing surface on the bar is convex where it contacts the post. The area of contact between the bar and the post is therefore restricted to a small

area. This will be point contact (in the absence of any localised deformation of the components) when the each of the relevant bearing surfaces is convex at the point of contact. Continued flexing of the knee joint beyond  $125^{\circ}$  results in rotation and sliding of the femoral component relative to the tibial component, about an axis which is approximately fixed. As the flex angle increases, the shear forces applied to the post by the bar, parallel to the plane of the resected tibia, increase.

Also as the flex angle increases and the bar 20 rotates relative to the post 26, the concave portion 32 of the bar moves rotationally towards the post. The area of contact between the concave portion and the post increases during continued rotation of the femoral component relative to the tibial component until the area of contact reaches a maximum at a flex angle of around  $150$  to  $155^{\circ}$ . The variation in the area of contact with angle of articulation is shown roughly in Figure 7.

CLAIMS:

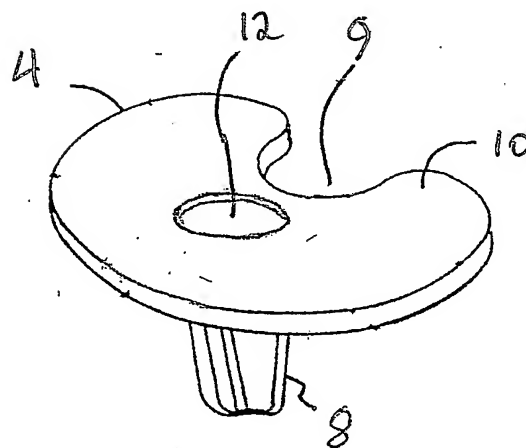
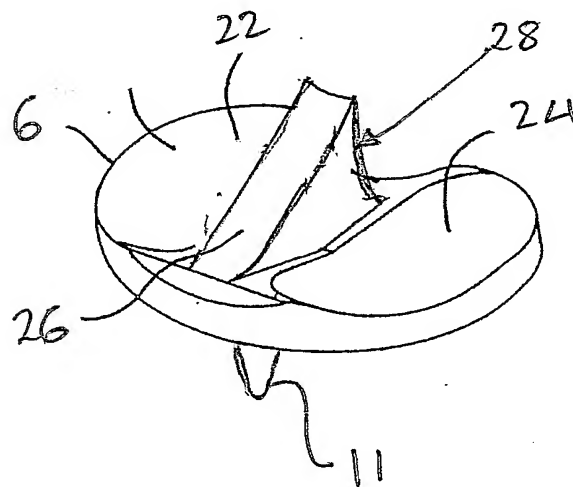
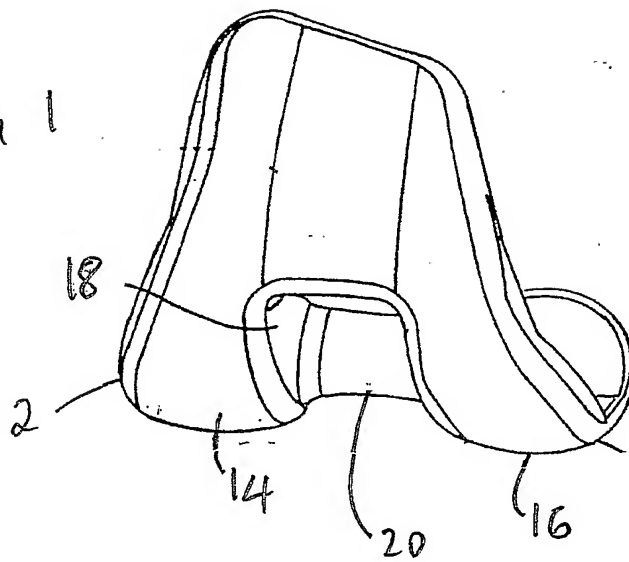
1. A knee joint prosthesis which comprises:
  - a. a tibial component which has a bone contact surface for contacting a patient's resected tibia, and an opposite bearing surface, and a post extending from the bearing surface in a direction generally away from the bone contact surface, and
  - b. a femoral component which has a bearing surface provided by medial and lateral condyles, and by a cam which is located between the condyles at or towards their posterior ends,

in which the condyles of the femoral bearing surface act against the bearing surface of the tibial component, directly or indirectly, during flexing of the knee and the cam on the femoral component acts against the post on the tibial component at high flex angles, the surface of the post which is contacted by the cam at high flex angles being convex when the post viewed generally perpendicular to the tibial bone contact and bearing surfaces, and the femoral bearing surface which is provided by the cam being concave where it contacts the convex surface of the post at high flex angles.

2. A knee joint prosthesis as claimed in claim 1, in which the cam is generally bar-like having a generally round cross-section when viewed along its length.
3. A knee joint prosthesis as claimed in claim 2, in which the cam is formed integrally with a web which extends between the condyles, in contact with the cam at a point where the cam does not contact the post during articulation of the joint.
4. A knee joint prosthesis as claimed in claim 2, in which when the maximum area of the cam which contacts the post extends to a point which is not more than 1.5 mm from the ends of the cam where it joins the condyles.

5. A knee joint prosthesis as claimed in claim 1, in which the bearing surface on the cam is configured so that the surface is concave where it acts against the post when the flex angle between the femur and the tibia is at least about  $130^{\circ}$ .
6. A knee joint prosthesis as claimed in claim 1, in which the tibial component comprises a tibial implant part for implantation in the tibia, and a bearing part, which can be positioned between the tibial implant part and the femoral component.
7. A knee joint prosthesis as claimed in claim 1, in which the depth of the concave portion of the cam, measured relative to the surface of the cam at each side of the concave portion, is at least about 0.5 mm.
8. A knee joint prosthesis as claimed in claim 1, in which the depth of the concave portion of the cam, measured relative to the surface of the cam at each side of the concave portion, is not more than 1.2 mm.
9. A knee joint prosthesis as claimed in claim 1, in which the radius of curvature at the anterior edge of the concave region is at least about 1.0 mm.
10. A knee joint prosthesis as claimed in claim 1, in which the radius of curvature at the at the anterior edge of the concave region is not more than about 3.0 mm.
11. A knee joint prosthesis as claimed in claim 1, in which the radius of curvature at the anterior edge is not more than about 6.0 mm.
12. A knee joint prosthesis as claimed in claim 1, in which the radius of curvature at the anterior edge is at least about 3.0 mm.

FIG 1



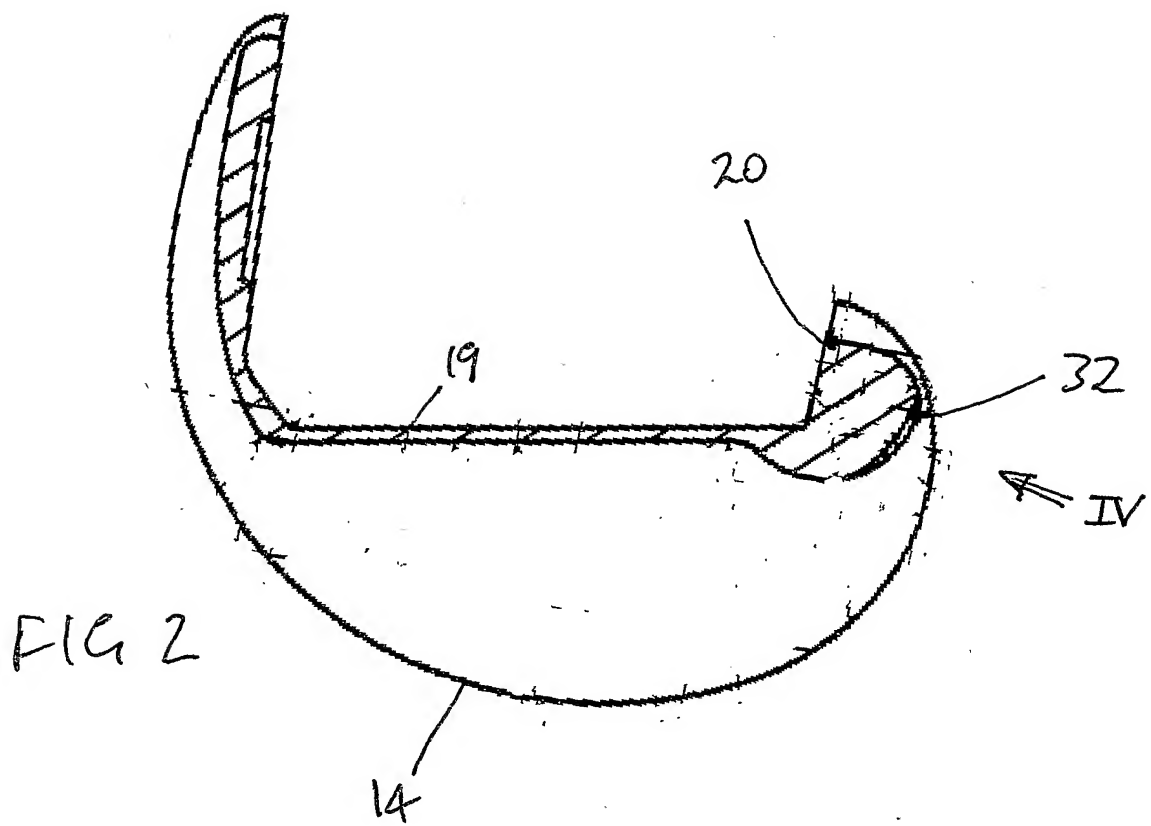


FIG 2

3/6

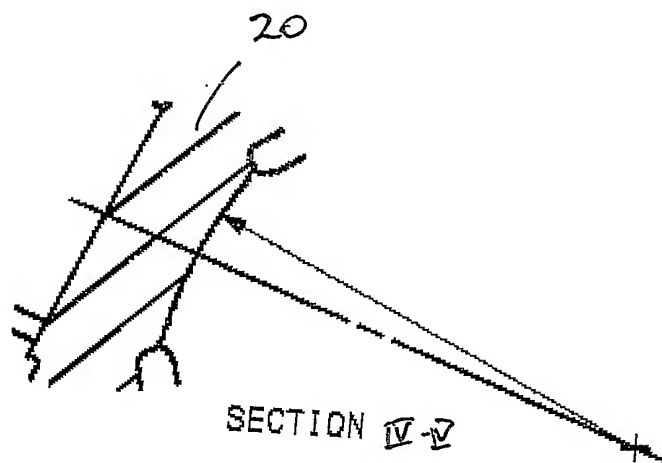
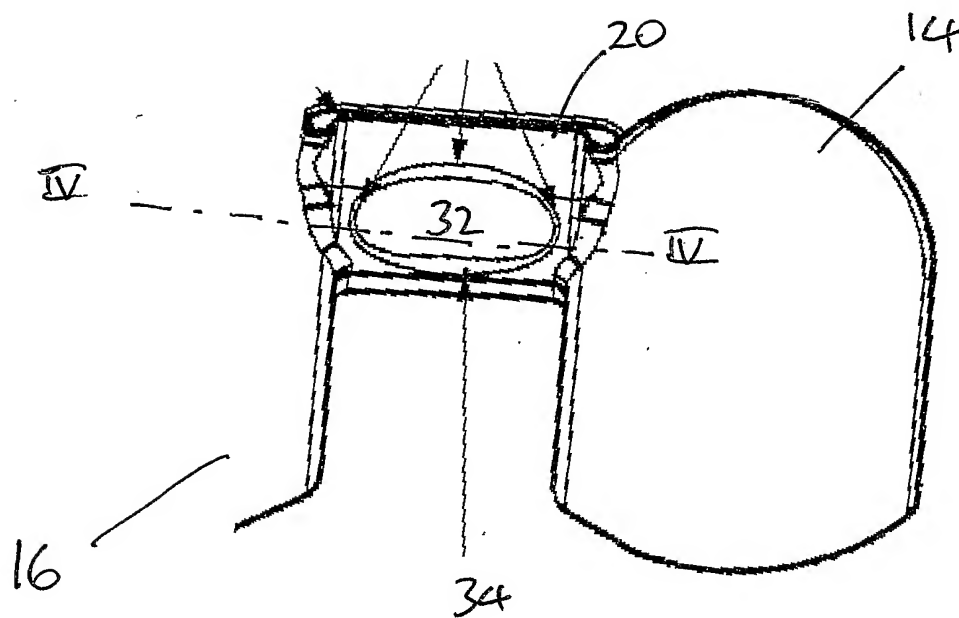


FIG 4

FIG 5a

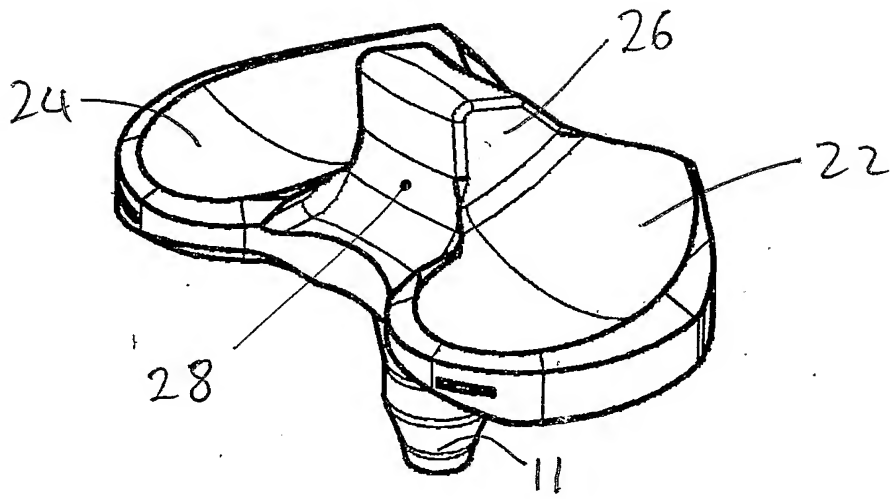
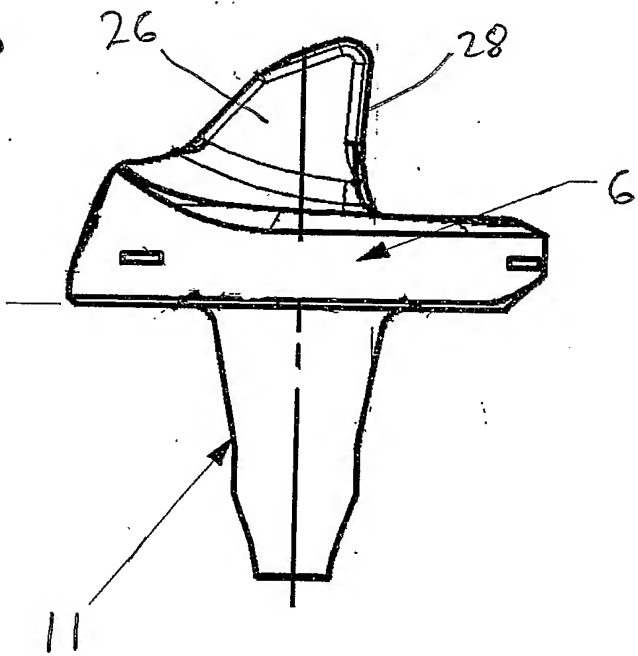
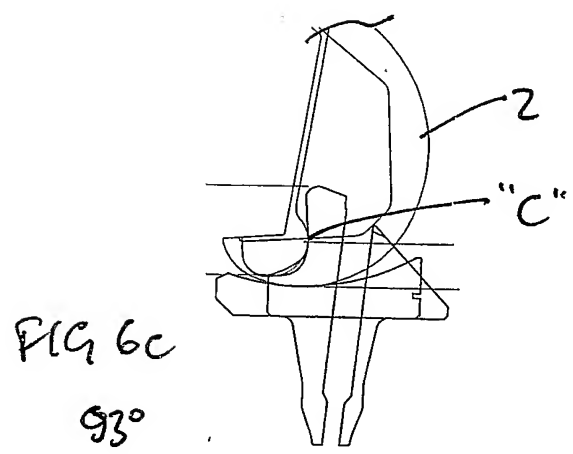
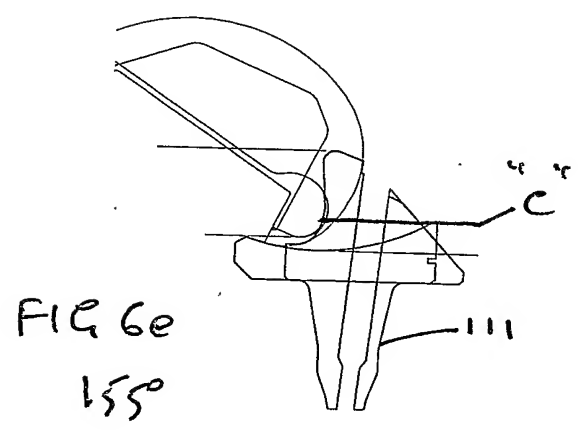
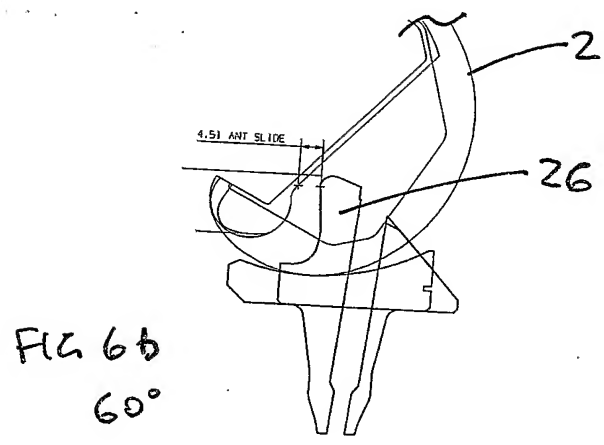
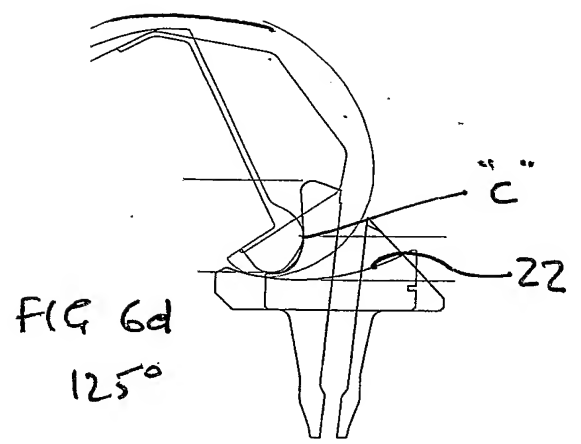
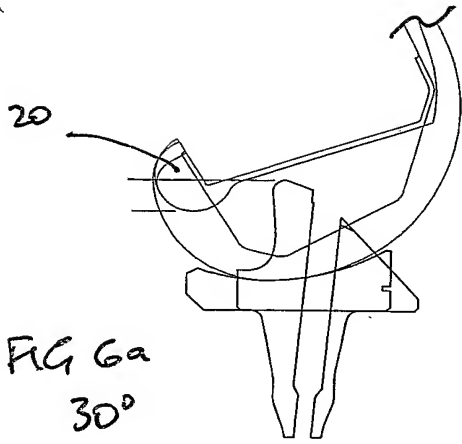


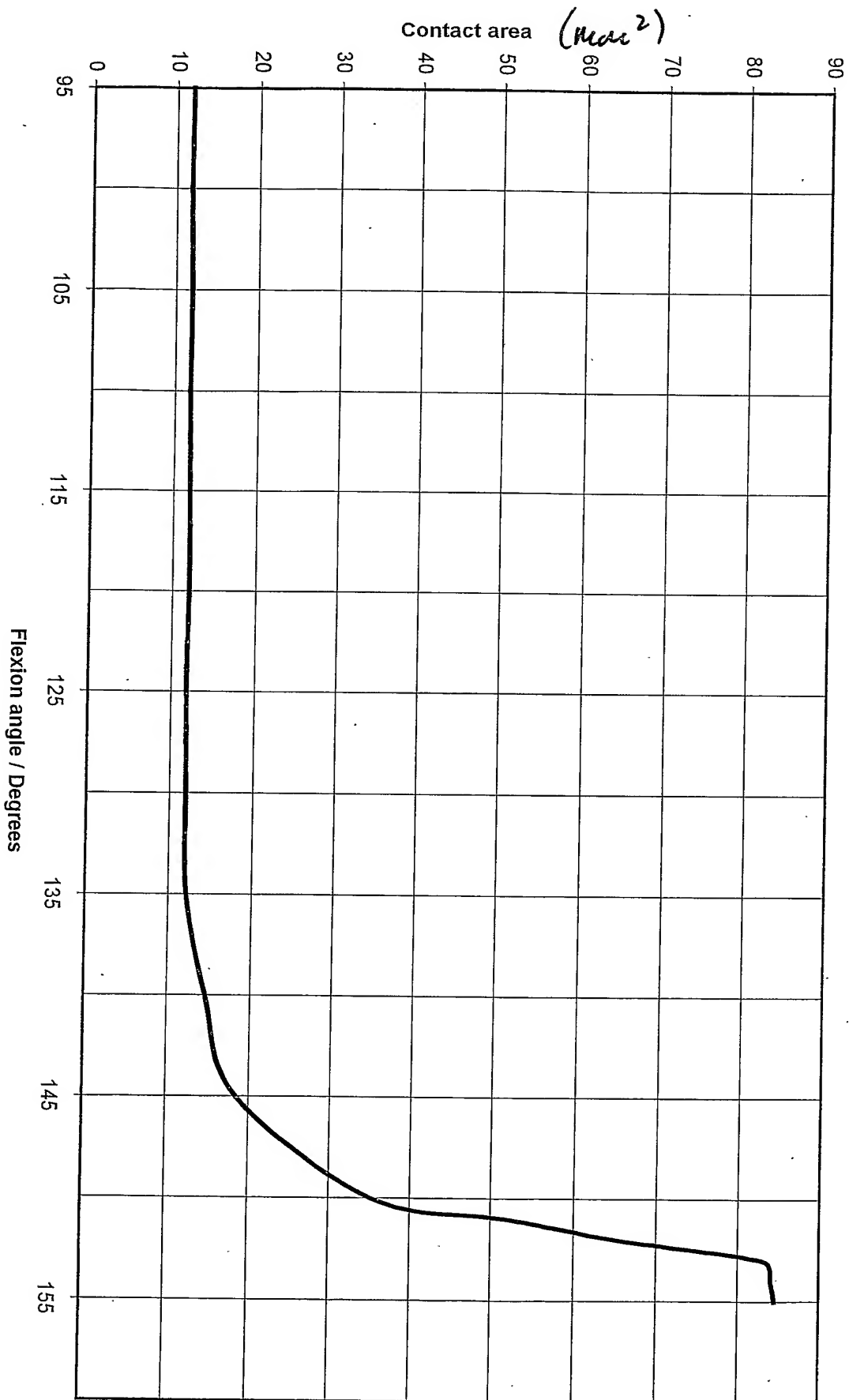
FIG 5b





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Variation of Contact area with Flexion angle



PL47